

a3 27. (ONCE AMENDED) A method for the production of SEQ ID NO:1 comprising culturing a host cell of claim 26 under conditions promoting expression, and recovering the polypeptide from the culture medium.

a4 30. (ONCE AMENDED) A method for the production of SEQ ID NO:1 comprising culturing a host cell of claim 29 under conditions promoting expression, and recovering the polypeptide from the culture medium.

### REMARKS

#### Status of Claims

Claims 1-41 are pending in this application. In the Office Action, the Office indicates that claims 10-22 and 33-41 are withdrawn from consideration as directed to nonelected inventions. Claims 1 and 2 are allowed, and claims 3-9 and 23-32 are rejected. With the present amendment, claims 10-22 and 33-41 are canceled and claims 3, 4, 6, 7, 24, 27, and 30 are amended. Thus, claims 1-5, 6-9, and 23-32 are pending with the present amendment.

#### Incorrect Recitation of vatD

As is explained in detail in the attached Declaration under 37 C.F.R. § 1.132, this application incorrectly refers to vatD, when the proper name for the identified sequence is vatE. This error exists because the name of the gene and corresponding protein was changed after Applicants filed their first application (provisional application 60/146,141). The error is corrected by the substitute specification submitted herewith, in which "vatD" is replaced by "vatE" throughout. Pursuant to 37 C.F.R. § 1.125(b)(2), Applicants submit a marked up copy of the specification showing where amendments were made. Applicants respectfully submit that no new matter is added by this substitute

specification. (See, Schering Corp. v. Amgen Inc., 55 U.S.P.Q.2d 1650, 222 F.3d 1347 (Fed. Cir. 2000)). In addition, pursuant to 37 C.F.R. § 1.25(b)(2), Applicants submit a marked-up copy of the specification showing where amendments were made.

Substitute Specification

As noted, the substitute specification includes the correction of *vatD* to *vatE*. In addition, Applicants have taken the opportunity to correct typographical errors in the specification, all of which are highlighted in red in the attached marked-up copy of the specification. Finally, Applicants have introduced paragraph numbering to the substitute specification. No new matter is added by any of these amendments.

Rejections under 35 U.S.C. § 112, First Paragraph

The Office rejects claims 6-7 and 23-25 under 35 U.S.C. § 112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Office asserts that claim 6 is drawn to a genus of *vatD* genes, but that the specification only teaches DNA encoding *vatD* from *Enterococcus faecium*. The Office also asserts that claim 6 is drawn to a subgenus of allelic DNAs that encode polypeptides comprising SEQ ID NO:1, but that the specification only discloses one allele within the scope of the genus. Claims 7 and 23-25, which ultimately depend from claim 6, were apparently rejected for the same reasons as claim 6.

In response, and without addressing the validity of the Office's assertions, Applicants have amended claim 6 to replace "vatD polypeptide" with "SEQ ID NO:1" and

"vatD polypeptide DNA" with "SEQ ID NO:2." It is respectfully submitted that this amendment obviates the rejection with regard to the specific points raised above.

The Office also rejects claims 6, 7, and 23-25, under 35 U.S.C. § 112, first paragraph, because it is alleged that the specification, while being enabling for DNA encoding a vatD of SEQ ID NO:2, does not reasonably provide enablement for DNA encoding vatD not homologous to SEQ ID NO:2. Claims 7 and 23-25, which ultimately depend from claim 6, were apparently rejected for the same reasons as claim 6.

As noted above, Applicants have amended claim 6. Applicants respectfully submit that this amendment obviates the rejection of claims 6, 7, and 23-25 under 35 U.S.C. § 112, first paragraph.

The Office also rejects claim 32 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was allegedly not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the claimed invention. In particular, the Office asserts that the plasmid deposited under Deposit No. I-2247 at CNCM is required to practice the claimed invention. In response, Applicants submit herewith a duly executed Deposit Declaration, obviating the rejection.

In view of the foregoing, Applicants respectfully request the withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Office also rejects claims 3-9 and 23-31 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention.

In particular, the Office rejects claim 3 because the exact hybridization conditions are unclear. In response, Applicants have amended claim 3 to replace "moderate" with "high" to describe the stringency. High stringent conditions are defined in the specification at page 8, line 24-27. It is respectfully submitted that this amendment obviates the rejection.

Claim 4 is rejected for failure to recite a colon after "NO" in line 3, and because the claim is unclear. In response, Applicants have amended claim 4 to add a colon, and in order to clarify its language so that its scope is clear, Applicants have amended the claim to clarify that the sequence is selected from any of SEQ ID NO:2 to NO:15. It is respectfully submitted that this amendment obviates the rejection.

Claim 5 is alleged to be unclear because SEQ ID NOs: 5 and 7 are amino acid sequences, but the claim is drawn to nucleic acid molecules and degenerate nucleic acid molecules. In response, claim 5 has been amended to more clearly set forth its metes and bounds. Applicants respectfully submit the amendment obviates the rejection, and respectfully request its withdrawal.

Claim 6 is alleged to be confusing for the recitation of "vatD polypeptide DNA." In response, Applicants have amended the claim to recite SEQ ID NO:2 instead of the cited phrase. It is respectfully submitted that this amendment obviates the rejection.

In view of the foregoing, Applicants respectfully request the withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

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Rejections under 35 U.S.C. § 102

The Office rejects claims 3-4 and 6 under 35 U.S.C. § 102(a) as allegedly being anticipated by Werner et al. (Antimicrobial Agents and Chemotherapy, Vol. 43, No. 7, July 1999, p. 1813-1814).

In response, Applicants respectfully traverse the rejection. However, without addressing the propriety of the substance of the rejection, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131, by Dr. Névine El Solh, an inventor for the above-identified application. The Declaration shows that Applicants' date of invention is prior to the effective publication date of Werner et al., and thus, Werner et al. is not prior art under 35 U.S.C. § 102(a). Applicants respectfully submit that the rejection is moot in view of the Declaration under 37 C.F.R. § 1.131, and respectfully request its withdrawal.

The Office also rejects claim 5 under 35 U.S.C. § 102(a) as allegedly being anticipated by Allignet et al. (WO 98/59058). In response, Applicants respectfully traverse the rejection. The disclosure relied upon in the rejection describes Applicants' own work, a fact that is described in the Declaration under 37 C.F.R. § 1.132 attached hereto. Thus, Applicants respectfully submit that WO 98/59058 is not available as a reference under 35 U.S.C. § 102(a), and Applicants respectfully request the withdrawal of this rejection.

Applicants take this opportunity to bring to the attention of the Office the existence of copending U.S. patent application serial number 09/099,932, which claims priority to U.S. provisional patent application serial no. 60/050,380 (to which WO 98/59058 also claims priority). Applicants also bring to the attention of the Office U.S. patent application serial no. 09/446,301, which is the U.S. national stage application of

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WO 98/59058. Copies of these applications are submitted herewith, and duly listed on a Form PTO-1449, but the Office is invited to review these copending applications, including their claims, at the Office.

The Office also rejects claims 6-7 and 23-25 under 35 U.S.C. § 102(b) over Rende-Fournier et al. (Antimicrobial Agents and Chemotherapy, Mar. 1998, p. 705-708). In response, Applicants respectfully traverse the rejection.

Rende-Fournier et al. discloses satA, which is analogous to vatD. However, as shown in the supporting Declaration under 37 C.F.R. § 1.132, the present invention is directed to vatE. Applicants initially used the term "vatD" to identify their newly discovered sequence, as reported in the priority application S.N. 60/146,141, but subsequently, the identified sequence became known as vatE. Thus, the pending claims are not anticipated by vatD. This fact is highlighted by Applicants' amendment of the claims to recite SEQ ID NO:1 (or SEQ ID NO:2), which are vatE sequences. Rende-Fournier et al. does not anticipate the claims, and Applicants respectfully request the withdrawal of the rejection.

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

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Respectfully submitted,

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Dated: April 8, 2002

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APPENDIX TO RESPONSE

**IN THE TITLE:**

Please change the title to read -- DETECTION OF A GENE, [vatD] vatE,  
ENCODING AN ACETYLTRANSFERASE INACTIVATING STREPTOGRAMIN --.

The claims are amended as follows:

3. (ONCE AMENDED) A purified nucleic acid molecule that hybridizes to either strand of a denatured, double-stranded DNA comprising the nucleic acid sequence of any one of claims 1 or 2 under conditions of [moderate] high stringency.
4. (ONCE AMENDED) The purified nucleic acid molecule as claimed in claim 3, wherein said isolated nucleic acid molecule is derived by in vitro mutagenesis from a sequence selected from SEQ ID NO:2 to NO: 15.
5. (ONCE AMENDED) A purified nucleic acid molecule encoding SEQ ID NOS: 5 or 7, or degenerate from SEQ ID NOS:[5,] 6[, 7,] or 8 as a result of the genetic code.
6. (ONCE AMENDED) A purified nucleic acid molecule, which encodes [vatD polypeptide] SEQ ID NO:1, an allelic variant of [vatD polypeptide DNA] SEQ ID NO:2, or a homolog of [vatD polypeptide DNA] SEQ ID NO:2.
7. (ONCE AMENDED) A recombinant vector that directs the expression of a nucleic acid molecule selected from the group consisting of the purified nucleic acid molecules of claims 1, 2, [5,] and 6.
24. (ONCE AMENDED) A method for the production of [vatD polypeptide] SEQ ID NO:1 comprising culturing a host cell of claim 23 under conditions promoting expression, and recovering the polypeptide from the culture medium.



27. (ONCE AMENDED) A method for the production of [vatD polypeptide]  
SEQ ID NO:1 comprising culturing a host cell of claim 26 under conditions promoting  
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30. (ONCE AMENDED) A method for the production of [vatD polypeptide]  
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